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Remarks

Claims 1, 6, 21, 29, 30, 33 and 34 have been amended. Claims 2 and 4 have been cancelled. Support for the amendments to the claims can be found in general throughout Applicants' Specification, and in particular, for example as follows: claims 1, 21 and 29, page 4, lines 20-21. No new matter has been added.

The August 22, 2006 Office action contained a Notice of References Cited. The Notice indicated that it was page 1 of 2. Applicants only received the first page of the Notice and respectfully request that the next action include any pages of the Notice of References Cited that were not include with the August 22<sup>nd</sup> Office action.

Applicants further note that an Information Disclosure Statement and a substitute form PTO-1449 were submitted on December 22, 2003. Applicants have not received a copy of the form PTO-1449 with the Examiner's initials indicating that the Examiner had considered the references listed thereon. Applicants respectfully request that the Examiner initial the form PTO-1449 and return the same to Applicants at the address of record. Applicants have included a copy of the previously submitted form PTO-1449 to assist in the Examiner's review.

Claim 33 stands rejected under 35 U.S.C. § 112.

The August 22<sup>nd</sup> Office action indicates that there is insufficient antecedent basis for the phrase "treating human" in line 1 of claim 33. Applicants note that the first line of claim 33 in its original form recited, "a method of treating a human." The phrase "treating a human" thus did not require antecedent basis. Accordingly, this asserted basis for rejecting claim 33 was improper. Applicants further submit that there is adequate support in the above-captioned application for the phrase treating a human (see, e.g., Applicants' Specification, page 3, lines 8-10 and page 7, lines 28-30), and therefore claim 33 in its original form satisfied the requirements of 35 U.S.C. § 112. Even so, to speed prosecution, Applicants have amended claim 33 to recite, "A method of using the tablet of claim 1." Applicants submit that the amendments to claim 33 render moot the rejection of claim 33 under 35 U.S.C. § 112, and respectfully request that it be withdrawn.

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Claims 1, 3, 5-26, 31 and 32 stand rejected under 35 U.S.C. § 102(b) over Murpani et al. (US 2003/0161875) or Needleman et al. (US 5,993,854).

Murpani et al. disclose tablets that dissolve in the mouth for use by patients who have difficulty swallowing. Murpani et al. specifically disclose that the tablets include a therapeutically effective amount of a drug that acts as a cyclooxygenase-2 enzyme (COX-2) inhibitor, a filler, and optionally other pharmaceutical acceptable excipients. Murpani et al. further disclose that the optional pharmaceutical excipients may be selected from binders, disintegrants, lubricants, glidants, coloring agents, flavoring agents and sweeteners that are chemically and physically compatible with COX-2 enzyme inhibitors.

Needleman et al. disclose an aroma releasing composition capable of effervescent and exothermic reaction when mixed with water to enhance the release of a volatile material, which is preferably a fragrance agent. Needleman et al. describe compounding an effervescent agent, an exothermic agent, and a volatile agent into an essentially anhydrous form.

Claim 1 is directed to a tablet that includes an effervescent composition that includes menthol, eucalyptus oil, and an effervescent agent, wherein the tablet dissolves in water having a temperature of at least 38°C to form a clear solution. "A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. 2131. Moreover, the reference must clearly and unequivocally disclose the claimed composition or direct those skilled in the art to the composition without any need for picking, choosing, and combining various disclosures (see, *In re Arkley*, 59 C.C.P.A. 804, 455 F.2d 586, 587, 172 U.S.P.Q. 524, 526 (CCPA 1972)). Murpani et al. disclose tablets that include a therapeutically effective amount of a drug that act as a COX-2 inhibitor and that disintegrate quickly in the mouth (see, Murpani et al., para. [0007]). Murpani et al. disclose that the tablets can include an excipient selected from the group consisting of binders, disintegrants, lubricants, glidants, coloring agents, flavoring agents and sweeteners (see, *Id.* at para. [0027]). Murpani et al. further disclose a long list of examples of the optional pharmaceutical excipients. Murpani et al. also disclose a long list of the optional disintegrants. Effervescent agents are disclosed as one example in a list of many optional disintegrants (see, *Id.* at para. [0030]). Menthol and eucalyptus oil

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are disclosed as being examples of two in a long list of optional flavoring agents (see, *Id.* at para. [0035]). Murpani et al. do not disclose an actual composition that includes menthol, eucalyptus oil or a combination of menthol and eucalyptus oil. Moreover, none of Murpani et al.'s example compositions include menthol or eucalyptus oil –let alone menthol, eucalyptus oil and an effervescent agent.

To arrive at the composition of claim 1, the skilled artisan upon reading Murpani et al. would have to make a series of selections. In particular, the skilled artisan would have to 1) decide to include two flavor agents, 2) select menthol and eucalyptus oil from the list of optional flavor agents, 3) decide to include an optional disintegrant, 4) select an effervescent agent from the long list of optional disintegrants, and then combine these ingredients to form a tablet that dissolves in water having a temperature of at least 38°C to form a clear solution. Nothing in Murpani et al. provides the requisite direction or motivation for the skilled artisan to make these particular selections. In particular, Murpani et al. do not direct the skilled artisan to specifically select menthol over any other flavoring agents in the long list of flavoring agents, to select eucalyptus oil over any other flavoring agents in the long list of flavoring agents, to select both menthol and eucalyptus, or to select an effervescent agent over any other disintegrant in their long list of disintegrants. Moreover, the mere fact that the skilled artisan would have to make these selections demonstrates that Murpani et al. do not teach the composition of claim 1. See, *In re Arkley*. Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 102(b) over Murpani et al. is unwarranted and respectfully request that it be withdrawn.

Claims 3, 5, 6-26 and 32 are distinguishable under 35 U.S.C. §102(b) over Murpani et al. for at least the same reasons as set forth above in distinguishing claim 1.

Claim 31 is directed to a carbonated mouthwash that includes water, menthol, and eucalyptus oil. Murpani et al. do not teach a mouthwash. Murpani et al. also do not teach a mouthwash that includes water, menthol and eucalyptus oil. Murpani et al. thus fail to teach required elements of claim 31. Applicants submit, therefore, that the rejection of claim 31 under 35 U.S.C. § 102 over Murpani et al. is unwarranted and respectfully request that it be withdrawn. To the extent the rejection is maintained, Applicants

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respectfully request that the next action identify, by reference to column and line number, the location in Murpani et al. of the requisite teaching.

We now turn to the rejection of claim 1 under 35 U.S.C. §102(b) over Needleman et al. Needleman et al. disclose aromatic compositions that include an effervescent agent, an exothermic agent and a volatile agent that is preferably a fragrance agent (see, Needleman et al., col. 2, lines 9-12). Needleman et al. disclose that the volatile agent can be a natural perfume that originates from natural plants and animals, and then disclose a long list of natural perfumes, which includes eucalyptus oil and menthol. *Id.* at col. 3, lines 21-60. Additionally, some of the example compositions of Needleman et al. include citric acid, sodium carbonate, sodium bicarbonate, an oil premix, PEG-150 and sorbitol. The oil premix includes 6.3 wt. % eucalyptus oil, 12.7 wt. % menthol, and 25.3 wt. % camphor, absorbed onto 55.7 wt % maltodextrin (see, *Id.* at col. 4, lines 1-39). Needleman et al. combine the oil premix with other ingredients to form a 30 gram tablet that includes 0.41 % menthol and 0.21 % eucalyptus oil. Needleman et al. do not teach a tablet that includes from 0.5 % by weight to about 10 % by weight menthol or from 0.5 % by weight to about 10 % by weight eucalyptus oil, as now required by claim 1. Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 102(b) over Needleman et al. has been overcome and Applicants respectfully request that it be withdrawn.

Claims 3, 5, 6-26 and 32 are distinguishable under 35 U.S.C. §102(b) over Needleman et al. for at least the same reasons as set forth above in distinguishing claim 1.

Claim 31 is directed to a carbonated mouthwash that includes water, menthol, and eucalyptus oil. Needleman et al. do not teach a mouthwash. Needleman et al. thus fail to teach a required element of claim 31. Applicants submit, therefore, that the rejection of claim 31 under 35 U.S.C. § 102 over Needleman et al. is unwarranted and respectfully request that it be withdrawn. To the extent the rejection is maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the location in Needleman et al. of the requisite teaching.

Claims 1, 27-30 stand rejected under 35 U.S.C. § 102(b) over Rockliffe et al. (US 4,471,871).

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Rockliffe et al. disclose a method of packing dry-to-the-touch articles within a closed, moisture impervious container. Rockliffe et al. further disclose the article can be presented in the form of a sheet, a wad of fabric, a tablet, or a powder. Rockliffe et al. explain the purpose is to retain the included non-aqueous liquid of the article until the article is moistened with water to provide a variety of functions.

Claim 1 is directed to a tablet that includes an effervescent composition that includes menthol, eucalyptus oil, and an effervescent agent, wherein the tablet dissolves in water having a temperature of at least 38°C to form a clear solution. "A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. 2131. Rockliffe et al. disclose articles that include a polymer matrix having a non-aqueous liquid that is releasable when the article is contacted with water (see, Rockliffe et al. at col. 1, lines 5-9). Rockliffe et al. also disclose that the non-aqueous liquid can include a solution of an organic solvent and a solute (see, *Id.* at col. 3, lines 44-46). Rockliffe et al. disclose a long list of solutes including flavor modifiers such as menthol and orange eucalyptus (see, *Id.* at col. 3, line 55 to col. 4, line 30). Rockliffe et al. do not teach effervescent compositions or disclose a composition that includes an effervescent agent. Rockliffe et al. also do not teach a composition that includes menthol, eucalyptus oil, and an effervescent agent. Furthermore, none of Rockliffe et al.'s example compositions include an effervescent agent, menthol and eucalyptus oil. Nothing in the record establishes anything to the contrary. Rockliffe et al. thus fail to teach a required element of claim 1. Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 102(b) over Rockliffe et al. is unwarranted and Applicants respectfully request that it be withdrawn. Should this rejection be maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the location in Rockliffe et al. of a teaching of the tablet of claim 1.

Claims 27-30 are distinguishable under 35 U.S.C. § 102(b) over Rockliffe et al. for at least the same reasons as set forth above in distinguishing claim 1.

Claims 1-36 stand rejected under 35 U.S.C. § 103 over Gioffre et al. (US 4,627,972) in view of Schobel (US 4,687,662).

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Gioffre et al. disclose dentifrice compositions that provide an effervescent action and mechanical cleansing action when introduced to the oral cavity in the presence of water. Gioffre et al. disclose that the dentifrice composition includes an essentially anhydrous dentifrice base medium and an inorganic oxide material containing an effective amount of an adsorbed gas.

Schobel discloses effervescent compositions in the form of tablets or powders that dissolve rapidly in cold water to yield an effervescent solution containing a completely dissolved therapeutic agent. Schobel further describes a dissolution test that involves placing a tablet in water at 22°C and observing the various rates of dissolution of the tablet.

Claim 1 is now directed to a tablet that includes an effervescent composition that includes menthol, eucalyptus oil, and an effervescent agent that includes an acid and a base, wherein the tablet dissolves in water having a temperature of at least 38°C to form a clear solution. In order to establish a *prima facie* case of obviousness, "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. 2142. It is undisputed that Gioffre et al. do not teach a tablet. Gioffre et al. also fail to teach a composition that includes an effervescent agent that includes an acid and a base. Instead Gioffre et al. disclose a dentifrice composition that contains at least one gas-containing inorganic oxide material and an anhydrous dentifrice base (see, Gioffre et al., col. 1, lines 4-8). The inorganic oxide material has an effective amount of adsorbed gas such that when the Gioffre et al. dentifrice is contacted with water, the adsorbed gas is released to provide an effervescent effect. Gioffre et al. explain that their composition does not need a chemical acid/base reaction to achieve effervescence. Thus Gioffre et al. teach away from an effervescent agent the includes an acid and a base.

Gioffre et al. disclose that their dentifrice can include flavoring agents and provides a long list of suitable flavoring agents, which includes eucalyptus oil and menthol. Gioffre et al. do not, however, teach an actual composition that includes eucalyptus oil, menthol and an effervescent agent and none of the Gioffre et al. examples include eucalyptus oil, menthol and an effervescent agent. In addition, nothing in Gioffre

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et al. specifically directs the skilled artisan to select eucalyptus oil, menthol and an effervescent agent and combine these ingredients to form a tablet.

Schobel does not cure the deficiencies of Gioffre et al. Schobel discloses effervescent compositions that are in the form of tablets and powders. Schobel does not teach or suggest anything about dentifrices such as those described in Gioffre et al. Schobel also does not teach or suggest forming dentifrices into tablets. Moreover, nothing in Schobel directs the skilled artisan to select menthol, eucalyptus, and an effervescent agent that includes an acid and a base and incorporate the same into a tablet that dissolves in water having a temperature of at least 38°C to form a clear solution. Accordingly, the skilled artisan would have no reason to do so. Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel is unwarranted and respectfully request that it be withdrawn.

Claims 2-36 are distinguishable under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel for at least the same reasons as set forth above in distinguishing claim 1.

Claims 31, 33, 34 and 36 are further distinguishable under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel for at least the following additional reasons.

Claim 31 is directed to a carbonated mouthwash that includes water, menthol, and eucalyptus oil. Neither Gioffre et al. nor Schobel teach or suggest a mouthwash. The proposed combination of Gioffre et al. and Schobel thus lacks a required element of claim 31. Accordingly, the record fails to establish a case of *prima facie* obviousness of claim 31. For at least this additional reason, Applicants submit that the rejection of claim 31 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel is unwarranted and respectfully request that it be withdrawn. To the extent the rejection is maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the location in Gioffre et al. or Schobel of the requisite teaching or suggestion.

Claim 33 is directed to a method of using the tablet of claim 1, where the method includes dissolving the tablet of claim 1 in water to form a clear solution, and inhaling vapors emitted by the solution. Neither Gioffre et al. nor Schobel teach or suggest inhaling vapors emitted by a solution formed by dissolving a tablet in water. The proposed combination of Gioffre et al. and Schobel thus lacks a required element of

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claim 33. Accordingly, a *prima facie* case of the obviousness of claim 33 has not been made. For at least this additional reason, Applicants submit that the rejection of claim 33 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel is unwarranted and respectfully request that it be withdrawn. To the extent the rejection is maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the location in Gioffre et al. or Schobel of the requisite teaching or suggestion.

Claim 34 is directed to a method of using the tablet of claim 1, where the method includes dissolving the tablet of claim 1 in water to form a clear solution, and gargling with the solution. Neither Gioffre et al. nor Schobel teach or suggest gargling with a solution formed by dissolving a tablet in water. The proposed combination of Gioffre et al. and Schobel thus lacks a required element of claim 34. Accordingly, the record fails to establish a case of *prima facie* obviousness of claim 34. For at least this additional reason, Applicants submit that the rejection of claim 34 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel is unwarranted and respectfully request that it be withdrawn. To the extent the rejection is maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the location in Gioffre et al. or Schobel of the requisite teaching or suggestion.

Claim 36 depends from claim 33 and further specifies that the water is boiling water. Neither Gioffre et al. nor Schobel teach or suggest dissolving a tablet in boiling water. The proposed combination of Gioffre et al. and Schobel thus lacks a required element of claim 36. Accordingly, a *prima facie* case of the obviousness of claim 36 has not been made. For at least this additional reason, Applicants submit that the rejection of claim 36 under 35 U.S.C. § 103 over Gioffre et al. in view of Schobel is unwarranted and respectfully request that it be withdrawn. To the extent the rejection is maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the location in Gioffre et al. or Schobel of the requisite teaching or suggestion.

Applicants note that the August 22<sup>nd</sup> Office action refers to a passage from Milkvy (US 3,772,431). Applicants further note that the cited passage from Milkvy does not teach or suggest that all effervescent compositions that produce a solution are uniquely



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desirable for use as a mouthwash. To the extent that a position to the contrary is being asserted in the August 22<sup>nd</sup> Office action, Applicants respectfully disagree.

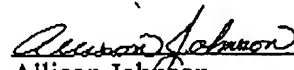
Applicants further note their express disagreement with all statements in the August 22<sup>nd</sup> Office action that are not expressly addressed herein.

The claims now pending in the application are in condition for allowance and such action is respectfully requested. The Examiner is invited to telephone the undersigned should a teleconference interview facilitate prosecution of the application.

Please charge any additional fees that may be required or credit any overpayment made to Deposit Account No. 501,171.

Respectfully submitted,

Date: November 21, 2006

  
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